IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Defendant" or "Teva"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 212212 ("the Teva ANDA") filed by or for the benefit of Defendant with the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendant seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' Symbicort® pharmaceutical products that are sold in the United States prior to the expiration of U.S. Patent Nos. 7,759,328 ("the '328 patent"), 8,143,239 ("the '239 patent"), 8,575,137 ("the '137 patent"), and 7,967,011 ("the '011 patent"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

Plaintiffs

2. Plaintiff AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Application No. 021929 for Symbicort.

Defendant

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a company organized and existing under the laws of the State of Delaware, with a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

BACKGROUND

The NDA

5. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 021929 for Symbicort (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol. Each Symbicort canister is formulated as a pressurized metered dose inhaler ("inhaler"). Symbicort is a prescription drug approved for the treatment of asthma in patients 6 years of age and older and maintenance treatment in patients with chronic obstructive pulmonary disease ("COPD") including bronchitis and emphysema. Budesonide and formoterol fumarate dihydrate are the two active ingredients in Symbicort. Symbicort is available in an 80 mcg budesonide/4.5 mcg formoterol fumarate dihydrate dosage and a 160 mcg budesonide/4.5 mcg formoterol fumarate dihydrate dosage.

6. FDA approved NDA No. 021929 on July 21, 2006.

7. Plaintiff AstraZeneca Pharmaceuticals LP sells and distributes Symbicort throughout the United States pursuant to NDA No. 021929.

The Patents-in-Suit

8. United States Patent No. 7,759,328 ("the '328 patent"), entitled "Composition for Inhalation," was issued by the United States Patent and Trademark Office ("the USPTO") on July 20, 2010, to AstraZeneca AB, upon assignment from the inventors Nayna Govind and Maria Marlow. The '328 patent claims, *inter alia*, a pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, 1,1,1,2,3,3,3-heptafluoropropane ("HFA227"), PVP K25 (polyvinyl pyrrolidone with a nominal K-value of 25) and PEG-1000 (polyethylene glycol with an average molecular weight of 1,000), wherein the formoterol fumarate dihydrate, budesonide, PVP K25 and PEG-1000 are present in certain concentrations. A true and correct copy of the '328 patent is attached as Exhibit A.

9. Plaintiff AstraZeneca AB has been and still is the owner of the '328 patent.

10. United States Patent No. 8,143,239 ("the '239 patent"), entitled "Composition for inhalation," was issued by the USPTO on March 27, 2012 to AstraZeneca AB upon assignment from inventors Nayna Govind and Maria Marlow. The claims of the '239 patent are directed to, *inter alia*, a pressurized metered dose inhaler containing a suspension composition comprising formoterol fumarate dihydrate, budesonide, HFA227, polyvinyl pyrrolidone ("PVP"), and polyethylene glycol ("PEG"), wherein the budesonide is present in a certain concentration and wherein an actuation of the inhaler delivers a certain dosage of formoterol fumarate dihydrate and budesonide. A true and correct copy of the '239 patent is attached as Exhibit B.

11. Plaintiff AstraZeneca AB has been and still is the owner of the '239 patent.

12. United States Patent No. 8,575,137 ("the '137 patent"), entitled "Composition for inhalation," was duly and legally issued by the USPTO on November 5, 2013, to AstraZeneca AB upon assignment from inventors Nayna Govind and Maria Marlow. The claims of the '137 patent are directed to, *inter alia*, a pharmaceutical suspension composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP, and PEG, wherein the budesonide, PVP, and PEG are present in certain concentrations. A true and correct copy of the '137 patent is attached as Exhibit C.

13. Plaintiff AstraZeneca AB has been and still is the owner of the '137 patent.

14. United States Patent No. 7,967,011 ("the '011 patent"), entitled "Inhalation device," was issued by the USPTO on June 28, 2011 to AstraZeneca AB upon assignment from inventors Darren Hodson and Jorgen Rasmussen. The claims of the '011 patent are directed to, *inter alia*, an actuator for an inhaler for delivering medicament by inhalation, the actuator comprising a main body tubular member; an ovoid, tubular mouthpiece; and a removable protection cap with release buttons. A true and correct copy of the '011 patent is attached as Exhibit D.

15. Plaintiff AstraZeneca AB has been and still is the owner of the '011 patent.

The Teva ANDA

16. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. has submitted or caused to be submitted ANDA No. 212212 to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale in the United States of Budesonide; Formoterol Fumarate Dihydrate, 0.08mg/inh; 0.0045mg/inh and Budesonide; Formoterol Fumarate Dihydrate, 0.16mg/inh; 0.0045mg/inh ("Teva's ANDA

Products"), generic versions of the two dosage forms of Symbicort, prior to the expiration of the patents-in-suit.

17. By letter dated September 14, 2018 ("Notice Letter"), Defendant Teva Pharmaceuticals USA, Inc. notified Plaintiffs that it had filed ANDA No. 212212 seeking approval to market Teva's ANDA Products and that Teva was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95. The Notice Letter, sent by Teva Pharmaceuticals USA, Inc., represented that it had submitted to FDA ANDA No. 212212 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Teva ANDA before the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, for Symbicort.

18. In its Notice Letter, and through its Paragraph IV certification in the Teva ANDA, Defendant Teva Pharmaceuticals USA, Inc. alleges that the patents-in-suit are invalid, not infringed by the commercial manufacture, use, or sale of Teva's ANDA Products, and/or unenforceable.

19. The Notice Letter included an Offer of Confidential Access to the Teva ANDA, subject to restrictions and terms set forth in the Notice Letter. The Offer of Confidential Access limited access to the Teva ANDA to outside attorneys only.

20. After negotiations regarding the terms of the Offer of Confidential Access, Plaintiffs received access to the Teva ANDA on October 3, 2018. Teva, however, has refused to provide samples of its proposed product.

21. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. assisted with and participated in the preparation and submission of the Teva ANDA, has provided

material support to the preparation and submission of the Teva ANDA, and intends to support the further prosecution of the Teva ANDA.

22. On information and belief, if FDA approves the Teva ANDA, Defendant Teva Pharmaceuticals USA, Inc. will manufacture, offer for sale, or sell Teva's ANDA Products within the United States, including within Delaware, or will import Teva's ANDA Products into the United States, including Delaware.

23. On information and belief, if FDA approves the Teva ANDA, Defendant Teva Pharmaceuticals USA, Inc. will actively induce or contribute to infringement by Teva's ANDA Products.

24. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Notice Letter.

JURISDICTION

25. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

26. Subject matter jurisdiction over this action is proper pursuant to the provisions of 28 U.S.C. §§ 1331 and 1338.

27. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation.

28. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. has a registered agent in the State of Delaware located at Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810.

29. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this judicial district.

30. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. has substantial, continuous, and systematic contacts with the State of Delaware including Defendant Teva Pharmaceuticals USA, Inc.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

31. This Court has personal jurisdiction over Defendant Teva Pharmaceuticals USA, Inc. by virtue of the fact that Teva Pharmaceuticals USA, Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in the State of Delaware, including acts of patent infringement with respect to Teva's ANDA Products. These acts have led and will lead to foreseeable harm and injury to AstraZeneca AB and AstraZeneca Pharmaceuticals, a Delaware corporation, in this judicial district. For example, on information and belief, upon receiving approval from the FDA, Defendant Teva Pharmaceuticals USA, Inc. will make, use, import, sell, and/or offer for sale Teva's ANDA Products, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

32. On information and belief, Defendant Teva Pharmaceuticals USA, Inc., and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Teva's ANDA Products, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this judicial district, and to derive substantial revenue therefrom.

33. On information and belief, Defendant Teva Pharmaceuticals USA, Inc., and/or its subsidiaries, affiliates or agents, intends to place Teva's ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this judicial district.

34. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of Delaware.

35. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, including, for example, in *Insys Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 18-cv-1308 (D. Del.); *Valeant Pharmaceuticals International et al. v. Actavis Laboratories FL, Inc.*, C.A. No. 18-cv-1288 (D. Del.); *Genentech, Inc. et al. v. Celltrion, Inc. et al.*, C.A. No. 18-cv-1025 (D. Del.); *Teva Pharmaceuticals USA, Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 17-cv-992 (D. Del.); and *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, C.A. No. 17-cv-249 (D. Del.).

36. This Court therefore has personal jurisdiction over Defendant Teva Pharmaceuticals USA, Inc.

VENUE

37. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

38. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

39. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. resides in the State of Delaware.

40. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is registered to do business in the State of Delaware.

41. On information and belief, a portion of Defendant Teva Pharmaceuticals USA, Inc.'s business is done in the State of Delaware.

42. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is in the business of bringing generic drugs to market, including filing Paragraph IV certifications, and triggering patent litigation, in which it challenges patents held by branded pharmaceutical companies, including in the State of Delaware.

43. Defendant Teva Pharmaceuticals USA, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction.

44. Venue is proper as to Defendant Teva Pharmaceuticals USA, Inc. because Teva Pharmaceuticals USA, Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, intends a future course of conduct that includes acts of patent infringement in the State of Delaware, and on information and belief resides in the State of Delaware. These acts have led and will lead to foreseeable harm and injury to AstraZeneca AB and AstraZeneca Pharmaceuticals LP, a Delaware corporation, in this judicial district. For example, on information and belief, upon receiving approval from the FDA, Defendant Teva Pharmaceuticals USA, Inc. will make, use, import, sell, and/or offer for sale

Teva's ANDA Products, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

COUNT I
INFRINGEMENT OF THE '328 PATENT

45. Plaintiffs incorporate by reference paragraphs 1-44 of this Complaint as if fully set forth herein.

46. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. submitted or caused the submission of ANDA No. 212212 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Teva's ANDA Products in the United States before the expiration of the '328 patent.

47. The Notice Letter informed Plaintiffs that Teva Pharmaceuticals USA, Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '328 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva ANDA Products.

48. Under 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 212212 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Products before the expiration of the '328 patent constitutes at least literal infringement of one or more claims of the '328 patent.

49. Defendant Teva Pharmaceuticals USA, Inc.'s commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Products would infringe the '328 patent and/or actively induce and/or contribute to infringement of the '328 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212212, Defendant Teva Pharmaceuticals USA, Inc. will make, use, offer to sell, or sell Teva's ANDA

Products within the United States, or will import Teva's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '328 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

50. On information and belief, upon FDA approval of ANDA No. 212212, Defendant Teva Pharmaceuticals USA, Inc. will market and distribute Teva's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. will also knowingly and intentionally accompany Teva's ANDA Products with a product label and product insert that will include instructions for using and administering the ANDA Products. Accordingly, Defendant Teva Pharmaceuticals USA, Inc. will induce health care professionals, resellers, pharmacies, and end users of Teva's ANDA Products to directly infringe one or more claims of the '328 patent. In addition, on information and belief, Defendant Teva Pharmaceuticals USA, Inc. will encourage acts of direct infringement with knowledge of the '328 patent and knowledge that they are encouraging infringement.

51. Defendant Teva Pharmaceuticals USA, Inc. had actual and constructive notice of the '328 patent prior to filing the Teva ANDA, and was aware that the filing of the Teva ANDA with the request for FDA approval prior to the expiration of the '328 patent would constitute an act of infringement of the '328 patent. Defendant Teva Pharmaceuticals USA, Inc. has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Teva's ANDA Products will not contribute to the infringement of and/or induce the infringement of the '328 patent.

52. In addition, Defendant Teva Pharmaceuticals USA, Inc. filed the Teva ANDA without adequate justification for asserting the '328 patent to be invalid, unenforceable, and/or

not infringed by the commercial manufacture, use, offer for sale, or sale of Teva's ANDA Products. Defendant Teva Pharmaceuticals USA, Inc.'s conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '328 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

53. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '328 PATENT

54. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-53 as if fully set forth herein.

55. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. On information and belief, if the Teva ANDA is approved, Teva's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendant Teva Pharmaceuticals USA, Inc. and/or its affiliates.

57. On information and belief, Defendant knows that health care professionals or patients will use Teva's ANDA Products in accordance with the labeling sought by the Teva ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '328 patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and/or (g).

58. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Teva's ANDA Products

complained of herein will begin immediately after the FDA approves the Teva ANDA. Any such conduct before the '328 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '328 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g).

59. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendant concerning liability for the infringement of the '328 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

60. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

61. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '239 PATENT

62. Plaintiffs incorporate by reference paragraphs 1-44 of this Complaint as if fully set forth herein.

63. On information and belief, Defendant submitted or caused the submission of ANDA No. 212212 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Teva's ANDA Products in the United States before the expiration of the '239 patent.

64. The Notice Letter informed Plaintiffs that Teva Pharmaceuticals USA, Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '239 patent is invalid, unenforceable, or will not be infringed by the commercial

manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Products.

65. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendant to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Products before the expiration of the '239 patent constitutes infringement of one or more claims of the '239 patent, either literally or under the doctrine of equivalents.

66. Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva's ANDA Products would infringe the '239 patent and/or actively induce and/or contribute to infringement of the '239 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212212, Defendant will make, use, offer to sell, or sell Teva's ANDA Products within the United States, or will import Teva's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '239 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

67. On information and belief, upon FDA approval of ANDA No. 212212, Defendant will market and distribute Teva's ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Teva's ANDA Products. On information and belief, Defendant will also knowingly and intentionally accompany Teva's ANDA Products with a product label and product insert that will include instructions for using and administering the ANDA Products. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of Teva's ANDA Products to directly infringe one or more claims of the '239 patent. In addition, on information and belief, Defendant will encourage acts of direct

infringement with knowledge of the ’239 patent and knowledge that they are encouraging infringement.

68. Defendant had actual and constructive notice of the ’239 patent prior to filing the Teva ANDA, and was aware that the filing of the Teva ANDA with the request for FDA approval prior to the expiration of the ’239 patent would constitute an act of infringement of the ’239 patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Products will not contribute to the infringement of and/or induce the infringement of the ’239 patent.

69. In addition, Defendant filed the Teva ANDA without adequate justification for asserting the ’239 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Products. Defendant’s conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the ’239 patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

70. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’239 PATENT

71. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-44 and 62-70 as if fully set forth herein.

72. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. On information and belief, if the Teva ANDA is approved, Teva’s ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States,

including in the State of Delaware, by or through Defendant Teva Pharmaceuticals USA, Inc. and/or its affiliates.

74. On information and belief, Defendant knows that health care professionals or patients will use Teva's ANDA Products in accordance with the labeling sought by the Teva ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '239 patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and/or (g).

75. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Teva ANDA Product complained of herein will begin immediately after the FDA approves the Teva ANDA. Any such conduct before the '239 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '239 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g).

76. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendant concerning liability for the infringement of the '239 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

77. Plaintiffs will be substantially and irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

78. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE ’137 PATENT

79. Plaintiffs incorporate by reference paragraphs 1-44 of this Complaint as if fully set forth herein.

80. On information and belief, Defendant submitted or caused the submission of ANDA No. 212212 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Teva’s ANDA Products in the United States before the expiration of the ’137 patent.

81. The Notice Letter informed Plaintiffs that Teva Pharmaceuticals USA, Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the ’137 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Products.

82. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendant to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Products before the expiration of the ’137 patent constitutes infringement of one or more claims of the ’137 patent, either literally or under the doctrine of equivalents.

83. Defendant’s commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Products would infringe the ’137 patent and/or actively induce and/or contribute to infringement of the ’137 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212212, Defendant will make, use, offer to sell, or sell Teva’s ANDA Products within the United States, or will import Teva’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the

infringement of one or more claims of the ’137 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g).

84. On information and belief, upon FDA approval of ANDA No. 212212, Defendant will market and distribute Teva’s ANDA Products to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of Teva’s ANDA Products. On information and belief, Defendant will also knowingly and intentionally accompany Teva’s ANDA Products with a product label and product insert that will include instructions for using and administering the ANDA Products. Accordingly, Defendant will induce health care professionals, resellers, pharmacies, and end users of Teva’s ANDA Products to directly infringe one or more claims of the ’137 patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the ’137 patent and knowledge that they are encouraging infringement.

85. Defendant had actual and constructive notice of the ’137 patent prior to filing the Teva ANDA, and was aware that the filing of the Teva ANDA with the request for FDA approval prior to the expiration of the ’137 patent would constitute an act of infringement of the ’137 patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Products will not contribute to the infringement of and/or induce the infringement of the ’137 patent.

86. In addition, Defendant filed the Teva ANDA without adequate justification for asserting the ’137 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Products. Defendant’s conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the ’137 patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

87. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '137 PATENT

88. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-44 and 79-87 as if fully set forth herein.

89. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. On information and belief, if the Teva ANDA is approved, Teva's ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendant Teva Pharmaceuticals USA, Inc. and/or its affiliates.

91. On information and belief, Defendant knows that health care professionals or patients will use Teva's ANDA Products in accordance with the labeling sought by the Teva ANDA and Defendant will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '137 patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and/or (g).

92. On information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Teva ANDA Product complained of herein will begin immediately after the FDA approves the Teva ANDA. Any such conduct before the '137 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '137 patent under one or more of 35 U.S.C. §§ 271(a) (b), (c), (f) and/or (g).

93. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendant concerning liability for the infringement of the ’137 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

94. Plaintiffs will be substantially and irreparably harmed by Defendant’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

95. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE ’011 PATENT

96. Plaintiffs incorporate by reference paragraphs 1-44 of this Complaint as if fully set forth herein.

97. On information and belief, Defendant submitted or caused the submission of ANDA No. 212212 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Teva’s ANDA Products in the United States before the expiration of the ’011 patent.

98. The Notice Letter informed Plaintiffs that Teva Pharmaceuticals USA, Inc. had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the ’011 patent will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Products.

99. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendant to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Products before the expiration of the ’011

patent constitutes infringement of one or more claims of the ’011 patent under at least the doctrine of equivalents.

100. Defendant’s commercial manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Products would infringe the ’011 patent and/or actively induce and/or contribute to infringement of the ’011 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212212, Defendant will make, use, offer to sell, or sell Teva’s ANDA Products within the United States, or will import Teva’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’011 patent.

101. Defendant had actual and constructive notice of the ’011 patent prior to filing the Teva ANDA, and was aware that the filing of the Teva ANDA with the request for FDA approval prior to the expiration of the ’011 patent would constitute an act of infringement of the ’011 patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Products will not contribute to the infringement of and/or induce the infringement of the ’011 patent under 35 U.S.C. § 271(a), (b), (c), and/or (f).

102. In addition, Defendant filed the Teva ANDA without adequate justification for asserting the ’011 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Products. Defendant’s conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the ’011 patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

103. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’011 PATENT

104. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1-44 and 96-103 as if fully set forth herein.

105. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

106. On information and belief, if the Teva ANDA is approved, Teva’s ANDA Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendant Teva Pharmaceuticals USA, Inc. and/or its affiliates.

107. On information and belief, Defendant’s infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Teva’s ANDA Products complained of herein will begin immediately after the FDA approves the Teva ANDA. Any such conduct before the ’011 patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’011 patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

108. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendant concerning liability for the infringement of the ’011 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

109. Plaintiffs will be substantially and irreparably harmed by Defendant’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

110. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products before the expiration of the '328 patent was an act of infringement of one or more claims of the '328 patent;

B. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products before the expiration of the '239 patent was an act of infringement of one or more claims of the '239 patent;

C. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products before the expiration of the '137 patent was an act of infringement of one or more claims of the '137 patent;

D. A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 212212 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products before the expiration of the '011 patent was an act of infringement of one or more claims of the '011 patent;

E. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or

importation into, the United States of Teva's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '328 patent;

F. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '239 patent;

G. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and/or (g), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '137 patent;

H. A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), and/or (f), Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '011 patent;

I. The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Defendant, its affiliates and subsidiaries, and all persons and entities acting in concert with Defendant from commercially manufacturing, using, offering for sale, or selling Teva's ANDA Products within the United States, or importing Teva's ANDA Products into the United States, until the expiration of the '328, '239, '137, and '011 patents;

J. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 212212 shall be no earlier than the last expiration date of any of the '328, '239, '137, and '011 patents, or any later expiration of exclusivity for any of the '328, '239, '137, and '011 patents, including any extensions or regulatory exclusivities;

K. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products, or any product that infringes the '328 patent, or induces or contributes to such conduct, prior to the expiration of the '328 patent;

L. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products, or any product that infringes the '239 patent, or induces or contributes to such conduct, prior to the expiration of the '239 patent;

M. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products, or any product that infringes the '137 patent, or induces or contributes to such conduct, prior to the expiration of the '137 patent;

N. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products, or any product that infringes the '011 patent, or induces or contributes to such conduct, prior to the expiration of the '011 patent;

O. The entry of judgment declaring that Defendant's acts render this case an exceptional case, and awarding Plaintiffs attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

P. An award to Plaintiffs of their costs and expenses in this action; and

Q. Such further and other relief as this Court may deem just and proper.

Dated: October 26, 2018

Respectfully submitted,

/s/ Daniel M. Silver

Michael P. Kelly (# 2295)
Daniel M. Silver (# 4758)
Alexandra M. Joyce (# 6423)
McCARTER & ENGLISH LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce @mccarter.com

Counsel for Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP

Christopher N. Sipes (*pro hac vice forthcoming*)
Gary M. Rubman (*pro hac vice forthcoming*)
Matthew Kudzin (*pro hac vice forthcoming*)
Anna Q. Han (*pro hac vice forthcoming*)
COVINGTON & BURLING LLP
One CityCenter, 850 Tenth St. NW
Washington, DC 20001
(202) 662-6000
csipes@cov.com
grubman@cov.com
mkudzin@cov.com
ahan@cov.com

Of Counsel for Plaintiffs